Syntermed™
Software solutions for medical imaging

K123646

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510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Syntermed, Inc.
Registration No. 1066019
Owner Operator I.D. 9041128
Device Regulation Number: 892.1200
Product Code: KPS
Classification Panel: Radiology
Voice: (888) 263-4446 ext 102, FAX: (714) 281-1290
Contact person: Kenneth F. Van Train
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130 Wieuca Road
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Atlanta, GA 30342
Date Summary Prepared: November 15, 2012

2. Medical Device:

Emory Cardiac Toolbox™ 4.0 - Display and Processing program for gated SPECT & PET myocardial perfusion studies executing on nuclear medicine computer systems and Windows PC's.

Classification Name – System, Tomography, Computed, Emission

3. Medical Device Equivalence:

Emory Cardiac Toolbox v3.1 K071503, Emory Cardiac Toolbox v2.0 K992450 (PERFEX), COR Analyzer developed by Rcadia K110071, CORRIDOR 4DM V2010 developed by INVIA K101279, and Coronary Flow Reserve (CFR) Quantification (cfrQuant) developed by University of Texas Medical School at Houston K113754.

4. Device Description:

The Emory Cardiac Toolbox™ 4.0 is used to display gated wall motion and for quantifying parameters of left-ventricular perfusion and function from gated SPECT & PET myocardial perfusion studies and for the evaluation of dynamic PET studies. These parameters are: perfusion, ejection fraction, end-diastolic volume, end-systolic volume, myocardial mass, transient ischemic dilatation (TID), analysis of coronary blood flow and coronary flow reserve, and assessment of cardiac mechanic dyssynchrony. In addition, the program offers the capability of providing the following diagnostic information: computer assisted visual scoring, prognostic information, and expert system image interpretation. The program can also be used for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface and for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM). The Emory Cardiac Toolbox can be used with any of the following Myocardial SPECT Protocols: Same Day and Two Day Sestamibi, Dual-Isotope (Tc-99m/Tl-201), Tetrofosmin, and Thallium, Rubidium-82, Rubidium-82 with CT-based attenuation correction, N-13-ammonia, FDG protocols, and user defined normal databases. This program was developed to run in the .NET operating system environment which can be executed on any PC, any nuclear medicine computer system, or through a web browser. In addition, the program can be used for the decision support in interpretation and automatic structured reporting of the study. The program processes the studies automatically, however, user verification of output is required and manual processing capability is provided.

5. Intended Use and Potential Adverse Effect on Health:

The Emory Cardiac Toolbox™ 4.0 software program should be used for the quantification of myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from SPECT & PET myocardial perfusion studies (EGS™), for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface, for the assessment of cardiac mechanical dyssynchrony using phase analysis, for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM), for the quantification of myocardial blood flow and coronary flow reserve, and for the decision support in interpretation (LVX) and automatic structured reporting of the study.

The interpretation provided by LVX is intended to assist a trained physician to analyze nuclear cardiology images. It was not meant to replace or eliminate the standard visual analysis of the gated SPECT & PET study. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, stress and/or rest EKG, quality control images, visual interpretation of the gated tomographic images, and quantitative and decision support interpretative results, prior to making his final interpretation. This comprehensive processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The expected accuracy of the initial program can be found in the multicenter trial results listed in the article by Vansant

et al Emory Cardiac Toolbox™ (CEqual®, EGS™) Version 2.0, Ref. 510(k) #: K992450 and Version 2.1, Ref. 510(k) #: K014033). The accuracy for modifications in version 4.0 for analysis of coronary blood flow, coronary flow reserve and for evaluation of the decision support system (LVX) in comparison to PERFEX results can be found in Item H (Testing & Validation) of this 510(k) submission. The physician should be aware of the accuracy when integrating the quantitative results for his final interpretation. Therefore, this program has no direct adverse effect on health since the results represent only a part of the information which the physician will utilize for his final interpretation. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been several medical device gated SPECT programs marketed in the past which perform similar functions to those performed by the Emory Cardiac Tool Box™ 2.0, 2.1, 2.6 and 3.1. These programs are all used for the purpose of displaying wall motion and deriving functional parameters for the diagnostic interpretation by a physician. The Emory Cardiac Tool Box™ 4.0 provides additional features for the analysis of coronary blood flow, and for the decision support in interpretation (LVX) and automatic structured reporting of the SPECT and PET study and we believe is substantially equivalent to Emory Cardiac Toolbox v3.1 K071503 for conversion from IDL to .NET; Emory Cardiac Toolbox v2.0 K992450 and COR Analyzer developed by Rcadia K110071 for decision support; and CORRIDOR 4DM V2010 developed by INVIA K101279 and Coronary Flow Reserve (CFR) Quantification (cfrQuant) developed by University of Texas Medical School at Houston K113754 for myocardial blood flow and coronary flow reserve. To our knowledge there have been no safety problems with the COR Analyzer decision support system which has been in the marketplace since January 31, 2011 and with CORRIDOR which has been marketed since August 4, 2010 or Coronary Flow Reserve (CFR) Quantification (cfrQuant) marketed since July 19, 2012.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the initial program, Emory Cardiac Toolbox™ 2.0, has been established in phantom and computer simulations studies, in-house trial validations which included an evaluation of left ventricular functional parameter calculations in 217 patients, and in a multicenter trial validation consisting of 80 patients. In addition, the computer assisted visual scoring, prognosis, expert system, and coronary fusion algorithms were successfully evaluated in 20, 504, 461, and 9 patients respectively. Additional validation of the Emory Cardiac Toolbox™ 2.1 program for development and validation of Rb-82 normal limits (n=176) and validation of PET tools for assessment of perfusion – metabolism match-mismatch (n=90) were successfully completed. Validation for the Emory Cardiac Toolbox™ 2.6 program included development and validation of N-13-ammonia normal limits (n= 144) and validation of the alignment method for 3D CT coronary artery onto the left ventricular 3D epicardial surface using phantom and

patient studies (n = 8). Validation for the Emory Cardiac Toolbox™ 3.1 program included development (phantom, animal, and patients n=4) and prospective validation of SPECT reconstruction in 10 patients and for phase analysis which included development in 90 normal patients and prospective validation in 75 additional patients. **Validation for the Emory Cardiac Toolbox™ 4.0 program included 301 patients used to validate the accuracy in deriving similar values for 14 perfusion, function and dyssynchrony variables from IDL to .NET conversion which demonstrated an accuracy greater than 99%, the coronary blood flow validation was conducted in 44 patient studies, and the decision support validation was conducted in 126 studies and these results are listed in Item H, Testing & Validation.** We contend that the method employed for the development and validation for the conversion from IDL to .NET operating system, the analysis of coronary blood flow and coronary flow reserve, and the decision support for interpretation of SPECT and PET data have proven its safety and effectiveness. In our opinion the additional features in Emory Cardiac Toolbox™ 4.0 for decision support for interpretation and coronary blood flow analysis are substantially equivalent to Emory Cardiac Toolbox v2.0 K992450 (PERFEX) and Rcadia's COR Analyzer K110071 for decision support (LVX) and INVIA's CORRIDOR 4DM V2010 K101279 and Coronary Flow Reserve (CFR) Quantification (cfrQuant) developed by University of Texas Medical School at Houston K113754 for coronary blood flow analysis which have all been cleared for marketing. The Emory Cardiac Toolbox™ 4.0 is intended for the same purpose as Emory Cardiac Toolbox™ 3.1 along with the additional purpose of decision support for interpretation, coronary blood flow, and coronary flow reserve analysis and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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February 22, 2013

Re: k123646
Emory Cardiac Toolbox 4.0
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computerized Tomography
Regulatory Class: Class II
Product Code: KPS
Dated: November 16, 2012
Received: November 27, 2012

Dear Dr. Van Train:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Director
Division Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K123646

Device Name:_Emory Cardiac Toolbox™ 4.0

Indications For Use:

The Emory Cardiac Toolbox™ 4.0 software program should be used for the quantification of myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from SPECT & PET myocardial perfusion studies (EGS™), for the 3D alignment of coronary artery models from CT coronary angiography onto the left ventricular 3D epicardial surface, for the assessment of cardiac mechanical dyssynchrony using phase analysis, for generation of the short axis, vertical, and horizontal long axis tomograms from the SPECT raw data using either filtered backprojection (FBP) or iterative reconstruction (MLEM/OSEM), for the quantification of myocardial blood flow and coronary flow reserve, and for the decision support in interpretation (LVX) and automatic structured reporting of the study.

The product is intended for use by trained nuclear technicians and nuclear medicine or nuclear cardiology physicians. The clinician remains ultimately responsible for the final interpretation and diagnosis based on standard practices and visual interpretation of all SPECT and PET data.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) k123646